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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,835	01/11/2002	Klaus List	2814/1-44	2848

7590 09/23/2003

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EXAMINER

METZMAIER, DANIEL S

ART UNIT	PAPER NUMBER
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1712

DATE MAILED: 09/23/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/045,835

Applicant(s)

LIST ET AL.

Examiner

Daniel S. Metzmaier

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 7-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 7-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claims 1, 3, and 7-61 are pending in the instant application. This action is responsive to the papers filed June 26, 2003.

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Germany on 11 January 2001. It is noted, however, that the application does not contain a certified copy of the German application, DE 101 00 867.8, as required by 35 U.S.C. 119(b). Said copy must be of record for a valid priority claim. The examiner notes applicants' post card receipt indicating a certified priority document and regrets any inconvenience.

Drawings

2. Applicant is required to submit a proposed drawing correction in reply to this Office action. Failure to timely submit the proposed drawing correction will be construed as non-responsive. Please see Form PTO-948.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 3 and 7-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how said compression shock occurs "behind an end of the enclosure and outside the enclosure". In the direction of flow, behind an end of the enclosure suggest inside the enclosure, ie, inside the nozzle,

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rather than the opposite, ie outside the nozzle. See page 11, lines 13-17, and contrast with original claim 4. Does applicants intend "behind an end of the enclosure or outside the enclosure"?

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 7, 9-11, 13-24, 26-29, 34-36, 39, 41-44 and 46-61 are rejected under 35 U.S.C. 102(b) as being anticipated by Wong et al., 4,972,830. Wong et al (figures and columns 3-8; particularly columns 7 and 8) disclose an inhalation device and methods of using said device. Wong et al (column 8, lines 5-9) discloses upstream pressures of 50 psig. 50 psig equates to about 3.4×10^5 Pa. Wong et al (column 8, lines 10 et seq) characterizes the function of the disclosed inhaler, wherein the gas stream is supersonic in the inlet restriction 86. Wong et al characterizes the stream flows without further significant change in volume or velocity until it reaches aperture 84 wherein upon expansion into chamber 20 undergoes shockwave. See Wong et al (figure 5) elements 96 and 92 and 94 for claims 3 and 36.

Wong et al (column 7, lines 51-53, 58, 66; and column 9, lines 11 et seq) discloses the incorporation of a medicament, solvent and the breaking of the particles into smaller particles.

The inhaler device is intended to be used at ambient room temperature. The temperature of the gas would have been inherent to the use of the Wong et al device. Inert gases such as N_2 are conventionally used for inhalers. Claim 17 is deemed inherent to the use of the Wong et al device.

Wong et al (column 8, lines 48) teaches the inhaler device forms a aerosolized mist having particle sizes of 1 to 3 microns and reads on applicants' preferred range. Wong et al (column 9) discloses the particles are broken up by the device. Since the resulting aerosol particle size is the same and the process is otherwise the same, the use of input particles having much larger particle sizes in the range of 10 to 100 times larger would have been inherent to those employed in the Wong et al process.

Solvents as used in Wong et al is indistinct from applicants claimed liquid carrier set forth in claim 26.

It is noted applicants' claims employ transitional language comprising, which does not exclude further steps and/or elements of the methods and device. Furthermore, the direction of flow has not been defined other than relative features of the device and or the direction of flow from higher pressure to lower pressure. Therefore, the path of flow reads on geometric paths other than linear. Claims 39-44 do not exclude the supply devices which supply both the gas and input particles from the same device. the use of an aerosol spray reads on storage tank.

The claimed feeding of the particles to the gas at subsonic velocity is implicit to feeding the medicament to the gas upon filling of the inhaler (see instant claim 7). Rest is subsonic velocity.

Claim 49 is included in the rejection as inherent since the reference contemplates pressures of up to 50 psi ($3.4 \cdot 10^5$ Pa). A prudent engineer would employ a vessel capable of withstanding pressures well in excess of the gas pressures employed, i.e., substantially $5 \cdot 10^5$ Pa, to advantageously remove the risk of explosion and to be safe.

7. Claims 1, 8-11, 13-24, 34, 39-40, 43-44 and 46-61 are rejected under 35 U.S.C. 102(b) as being anticipated by Boiarski et al., 4,268,460. Boiarski et al (figures; column 1, lines 24 et seq; column 6, lines 59 et seq; column 7, lines 33 et seq) discloses a nebulizer wherein the particles are reduced in size by being accelerated to supersonic velocity followed by a shock wave resulting from the supersonic to subsonic transition.

Since the apparatus has application in the treatment of lung therapy, the temperature would be expected to be about room temperature for breathability by the user. The limitations of claims 13-16 are deemed inherent to the use of the Boiarski et al apparatus.

For the limitations of claims 18-23 and 55-60, please see figure 4-8.

Claim 49 is included in the rejection as inherent since the reference contemplates pressures of up to 60 psi ($4.1 \cdot 10^5$ Pa). A prudent engineer would employ a vessel capable of withstanding pressures well in excess of the gas pressures employed, i.e., $5 \cdot 10^5$ Pa, to advantageously remove the risk of explosion and to be safe.

8. Claims 1, 3, 9, 13, 17, 24, 31-32, 34-46, 50, 54 and 61 are rejected under 35 U.S.C. 102(b) as being anticipated by Wagner, US 4,294,208. See figure 2 and

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columns 2-4. The temperature range claimed is broad enough to encompass the fuel-air mix (column 2, line 50).

9. Von Rosenberg, Jr. et al, US 4,278,446, is considered cumulative for at least claims having a DeLaval nozzle, semi-solid or solid particles and water as a carrier. Please not designation 26 in the figure which correspond to shock waves. Designation 20 is a pump. Coal and/or char are both feed into a gas stream.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 13-16, 18-20, 50-53 and 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al., 4,972,830. Wong et al discloses inhaler devices

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and methods of using said inhaler devices in the above rejection, which is incorporated herein by reference.

To the extent Wong et al differs from the claims in the temperature of the gas or the particle size of the input particles, said parameters are dependent on the particular composition and medicament employed and/or the amount of agitation acted on the gas input particles prior to discharging the inhaler composition from the pressurized container.

It would have been obvious to one of ordinary skilled in the art at the time of applicants' invention to agitate and vary the input particles size in the gas prior to discharge for the advantage of a more finely dispersed aerosol. It would have been obvious to one of ordinary skilled in the art at the time of applicants' invention to vary the temperature of the gas at rest as a result of normal use in varied ambient temperatures.

13. Claims 24-30 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al., 4,972,830, as applied to claims 1, 7, 9-11, 13-24, 26-29, 34-36, 39, 41-44 and 46-61, above, and further in view of Sallmann et al, 5,096,917, or Gleason et al, 4,552,893. Wong et al discloses methods and apparatus for aerosolizing materials as set forth in the above anticipation and obviousness rejections by/over the same. Said characterizations have been incorporated herein by reference.

Wong et al differs from the claims in the use of water, alcohol, a semi-solid, solid active ingredients.

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Sallmann et al (column 9, lines 48 et seq ; column 10, lines 22 et seq ; and example A) discloses aerosol compositions wherein the compositions may be dispensed by a metered dose apparatus. Sallmann et al (column 10, lines 22 et seq) teaches the use of micronized particles having advantageously less than 5 micron particle sizes; solutions, suspensions and emulsions as carriers; and pharmaceutical excipients including water and ethanol as conventional.

Gleason et al (column 5, lines 58 et seq, and column 6, lines 17 et seq) discloses pharmaceutical compositions may be in a carrier such as a solution or suspension of water or alcohol among others. Gleason et al teaches the compositions may be dispensed by a pressurized aerosol.

These references are combinable because they teach aerosol compositions and aerosol apparatus for dispensing said compositions. It would have been obvious to one of ordinary skilled in the art at the time of applicants' invention to employ the conventions compositions employing a solution or suspension in a water based carrier or an alcohol based carrier taught to be conventional in the Sallmann et al or Gleason et al references in the apparatus and methods of the Wong et al reference. Furthermore, it would have been obvious to one of ordinary skilled in the art at the time of applicants' invention to employ a micronized powder taught in the Sallmann et al reference in the apparatus and methods of the Wong et al reference.

14. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al., 4,972,830, as applied to claims 1, 7, 9-11, 13-24, 26-29, 34-36, 39, 41-44 and 46-61, above, and further in view of Sanders, "Principles of Aerosol Technology", pages

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18-33. Wong et al discloses methods and apparatus for aerosolizing materials as set forth in the above anticipation and obviousness rejections by/over the same. Said characterizations have been incorporated herein by reference.

Wong et al differs from the claims in the use of a gas at a pressure of substantially $5 \cdot 10^5$ Pa.

Wong et al (column 7, lines 61-63) teaches the pressure of the gas may be dependent on the container employed and (column 8, lines 4-5) that the ratio of the gas pressure to the ambient pressures be greater than the critical pressure ratio.

Sanders teach a number of propellants including Freon 12 that has a pressure that is substantially $5 \cdot 10^5$ Pa.

Response to Arguments

15. Applicant's arguments filed June 26, 2003 have been fully considered but they are not persuasive.

16. Applicants (page 21) assert Wong et al discloses a method and apparatus having, which hits a bluff (24) that causes compression shocks. Applicants assert the only compression shocks occur when the flow hits the bluff. This has not been deemed persuasive since column 8, lines 44-66, of Wong et al teaches that the vortex is formed from hitting the bluff and a single large exiting vortex is formed comprising fluid flow at supersonic velocity due to compression of the vortices flowing through the orifice and due to the pressure difference across the orifice being greater than the critical pressure. The vortices are formed by hitting the bluff (24) followed by a second compression and expansion. Since the difference is greater than the critical pressure, one skilled in the

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art would expect a compression shock as claimed. The instant claims do not exclude the further arrangements in the Wong et al reference.

Applicants' arguments regarding the location of the compression shocks outside of the enclosure are unclear since the claims appear to include both inside and outside compression shocks. See above issues regarding indefiniteness.

17. Applicants (page 22) assert the Boiarski et al does not employ a Laval nozzle and supersonic speeds cannot exist downstream of the unwidened opening 70. This has not been deemed persuasive since opening 70 has an infinite widening downstream of opening 70. The supersonic flow and the compression shock and subsonic flow is dependent of the surrounding atmosphere immediately adjacent to opening 70. Applicants' arguments do not rebut or refute the clear teachings of the Boiarski et al reference.

Furthermore, applicants' arguments are in conflict with the specification at page 11, lines 13-17, wherein compression shocks outside of an enclosure are also possible.

18. Applicants (pages 22 and 23) assert Wagner does not teach compression shocks outside of an enclosure. Applicants' arguments regarding the location of the compression shocks outside of the enclosure are unclear. The claims appear to include both inside and outside compression shocks and therefore read on the Wagner reference. See above issues regarding indefiniteness.

19. Applicants' (pages 23-24) arguments regarding the obviousness of Wong et al based on the preceding arguments have been addressed in the above response.

Conclusion

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel S. Metzmaier whose telephone number is (703) 308-0451. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Dawson can be reached on (703) 308-2340. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.


Daniel S. Metzmaier
Primary Examiner
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